# Safety Data Sheet
acc. to OSHA HCS

Printing date 06/12/2014 Version number 6 Reviewed on 01/10/2014

## 1 Identification

· **Product identifier**

· **Trade name:** **Virtual Heavy Fast / Regular Catalyst**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the mixture** Dental impression material

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102

· **Information department:** Quality Assurance / Regulatory Affairs
· **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General MSDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

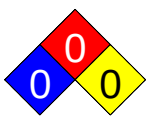
## 2 Hazard(s) identification

· **Classification of the substance or mixture**

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
· **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
· **Classification system:**
· **NFPA ratings (scale 0 - 4)**




Health = 0
Fire = 0
Reactivity = 0

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· **HMIS-ratings (scale 0 - 4)**




*Health = *0*
*Fire = 0*
*Reactivity = 0*

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

## 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

| · **Dangerous components:** | | |
|---|---|---|
| 14464-46-1 | cristobalite | 10-<25% |
| 9016-45-9 | 4-Nonylphenyl-polyethylene glycol | 0.1-<1% |

| · **SVHC** | |
|---|---|
| 9016-45-9 | 4-Nonylphenyl-polyethylene glycol |

## 4 First-aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:** Seek medical treatment.
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

## 5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

## 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
See Section 7 for information on safe handling.

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See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

## 7 Handling and storage

· **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
· **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
· **Breathing equipment:** Not required.
· **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses



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## 9 Physical and chemical properties

| | |
|---|---|
| · **Information on basic physical and chemical properties** | |
| · **General Information** | |
| · **Appearance:** | |
| **Form:** | Viscous |
| **Color:** | White |
| · **Odor:** | Odorless |
| · **Odour threshold:** | Not determined. |
| · **pH-value:** | Not applicable. |
| · **Change in condition** | |
| **Melting point/Melting range:** | Undetermined. |
| **Boiling point/Boiling range:** | Undetermined. |
| · **Flash point:** | Not applicable. |
| · **Flammability (solid, gaseous):** | Not applicable. |
| · **Auto igniting:** | Product is not selfigniting. |
| · **Danger of explosion:** | Product does not present an explosion hazard. |
| · **Explosion limits:** | |
| **Lower:** | Not determined. |
| **Upper:** | Not determined. |
| · **Vapor pressure:** | Not determined. |
| · **Density:** | Not determined. |
| · **Relative density** | Not determined. |
| · **Vapour density** | Not determined. |
| · **Evaporation rate** | Not determined. |
| · **Solubility in / Miscibility with** | |
| **Water:** | Not miscible or difficult to mix. |
| · **Partition coefficient (n-octanol/water):** | Not determined. |
| · **Viscosity:** | |
| **Dynamic:** | Not determined. |
| **Kinematic:** | Not determined. |
| · **Other information** | No further relevant information available. |

## 10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability** Stable under normal handling and storage conditions.
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** None under normal conditions of storage and use.



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## 11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:

· **Carcinogenic categories**

| · **IARC (International Agency for Research on Cancer)** | | |
|---|---|---|
| 14464-46-1 | cristobalite | 1 |

| · **NTP (National Toxicology Program)** | | |
|---|---|---|
| 14464-46-1 | cristobalite | K |

## 12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

· **Waste treatment methods**
· **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

· **UN-Number**
· **DOT, ADR, ADN, IMDG, IATA** Void

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| | |
|---|---|
| · **UN proper shipping name**<br>· **DOT, ADR, ADN, IMDG, IATA** | Void |
| · **Transport hazard class(es)**<br>· **DOT, ADR, ADN, IMDG, IATA**<br>· **Class** | Void |
| · **Packing group**<br>· **DOT, ADR, IMDG, IATA** | Void |
| · **Environmental hazards:**<br>· **Marine pollutant:** | No |
| · **Special precautions for user** | Not applicable. |
| · **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | Not applicable. |
| · **Transport/Additional information:** | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |

## 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

| | |
|---|---|
| 14464-46-1 | cristobalite |

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

| | | |
|---|---|---|
| 14464-46-1 | cristobalite | A2 |

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

| | |
|---|---|
| 14464-46-1 | cristobalite |

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard information:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 06/12/2014 / 5